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DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 1120890

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215-3215
Telephone: (410) 773-5454

Warning Letter

03-BLT-22

July 23, 2003

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Wayne L. Grube, Sr., President
Aerosol and Liquid Packaging, Inc.
715 S. Haven Street
Baltimore, MD 21224

Dear Mr. Grube:

During an inspection of your manufacturing facility located in Baltimore, MD conducted on May 13-21, 2003, our investigator determined that your establishment manufactures liquid bandages and skin protectant salve. Liquid Bandages are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 USC 321(h)]. Skin protectant salve is a drug as defined in Section 201(g) of the Act [21 USC 321(g)].

The inspection revealed that the devices manufactured at your facility are adulterated within the meaning of 501(h) of the Act [21 USC 351(h)] in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System regulations for medical devices specified in 21 Code of Federal Regulations, Part 820 [21 CFR Part 820].

The deviations from QSR [21 CFR § 820] found during the inspection, and reported on the list of Inspectional Observations, Form FDA-483, presented at the conclusion of the inspection, include the following:

1. The device history record (DHR) does not contain documentation that required cleaning of the production equipment was performed as required by 21 CFR 820.70(e) and 820.184.

2. Obsolete procedures were not removed from all points of use or otherwise prevented from unintended use as required by 21 CFR 820.40(a).

3. The device history record (DHR) does not contain the primary identification label and labeling used as required by 21 CFR 820.120(d) and 820.184(e).

The following violations were noted during the review of the documents collected by our investigator at your firm after the form FDA-483 was issued to you and therefore were not documented on the form FDA-483:

4. Failure to follow your written sampling plan for the acceptance of component received as required by 21 CFR 820.250(b). Your "Procedure For Sampling Plan And Inspection Specifications of Components For Medtech 1 ox. New Skin Spray U.S. Version and Canadian Version" requires the use of [redacted] The sample size for th[redacted]units received under Purchase order [redacted] using [redacted]

5. Failure to identify, document, evaluate, segregate and investigate non-conforming material as required by 21 CFR 820.90(a). Our review of the documents collected at your firm during the inspection revealed lot L 28720 did not meet in-process testing for pressure on multiple occasions, and the device history record does not indicate the non-conformity was evaluated and investigated. In addition, review of the inspection results of incoming components reveals that lot 35 of the [redacted] inspected on 7/10/02 did not meet specifications. The sampling plan described in the above paragraph calls for the lot to be rejected if [redacted]r more defects are found and, according to the inspection document[redacted]ritical defects were found.

The above identification of violations is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice and Quality System Regulations. Federal agencies are advised of the issuance of all warning letters concerning drugs and devices so that they may take this information into account when considering the award of contracts.

We acknowledge receipt your response letter dated May 22, 2003, to the observations noted on the FDA-483 issued on May 21, 2003. Your response, however, does not provide enough information to determine if it is adequate to correct the violations noted on the FDA-483. Your response will be added to your official file and the corrective actions outlined in the response will be verified during the next inspection of your facility.

You should take prompt action to correct these deviations. Failure to correct these deviations promptly may result in regulatory action without further notice. These included seizure, injunction, civil monetary penalties and prosecution.

In addition, you should be advised, on June 4, 2003, the Food and Drug Administration (FDA) issued a final rule in the form of a final monograph establishing conditions under which over-the-counter (OTC) skin protectant drug products are generally recognized as safe and effective and not misbranded as part of the ongoing review of OTC drug products conducted by FDA. The final monograph includes OTC skin protectant drug products for minor cuts, scrapes, burns, chapped skin and lips, poison ivy, poison oak, poison sumac, and insect bites. The rule is effective June 4, 2004. You may find a copy of the Federal Register Notice at http://www.fda.gov/OHRMS/DOCKETS/98fr/060403b.htm .

Please notify the Baltimore District office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of these or similar violations. Your reply should be sent to the Food and Drug Administration, Baltimore District Office, 6000 Metro Drive, Suite 101, Baltimore, MD 21215, Attention: Steven B. Barber, Compliance Officer.

Sincerely,

Nathaniel B. Acting for Lee Bowers

Lee Bowers
District Director